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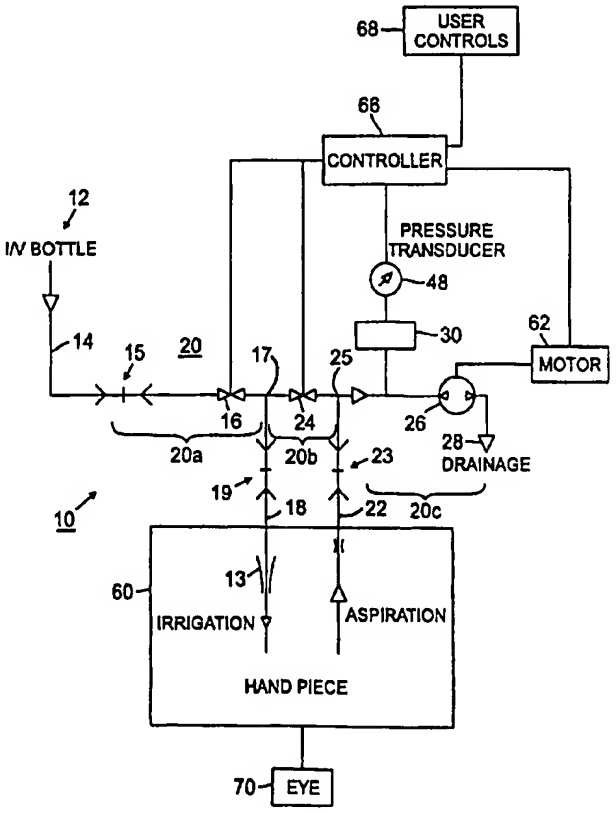
(54) Title: CONTROLLING PRESSURE IN THE EYE DURING SURGERY

(57) Abstract

Fluid pressure in the eye is monitored by detecting vacuum-induced deflections of a diaphragm on a reservoir that forms an integral part of the tube set through which fluid is supplied to and withdrawn from the eye. The rate at which fluid is withdrawn (i.e., aspirated) from the eye is controlled based on the detected deflections of the diaphragm. As a result, the detection component (e.g., a pressure sensor) is isolated from the fluids in the tube set by the diaphragm. This minimizes both the risk of contaminating the sensor with fluid aspirated from the patient, and the danger of so-called "cross-contamination" in which subsequent patients are exposed to the aspirated fluid of a prior patient.



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CONTROLLING PRESSURE IN THE EYE DURING SURGERY

Background of the Invention

This invention relates to monitoring and controlling the pressure of fluid in the eye during eye surgery.

The anterior region of the eye is a small, fluid-filled chamber. During surgery, fluid balance in the eye is maintained by supplying irrigation fluid to the eye and aspirating fluid from the eye using a surgical instrument. One such instrument, particularly useful in removing cataracts, is a phaco-emulsification instrument, which includes an ultrasonically vibrated hypodermic needle inserted into an incision in the eye to break up the cataract lens. The lens fragments and aspirated fluid are removed by suction through the needle. Typically, the surgical instrument is connected to the source of irrigation fluid and a drainage bag with a tube set that includes a series of individual, interconnected irrigation and aspiration tubes. After the procedure has been completed, the tube set is disassembled, and is either sterilized and reused or replaced with a new set of tubes for the next procedure.

To avoid damaging the eye, the rate at which irrigating fluid is supplied to the eye and aspirated (generally by inducing a vacuum in the aspiration tube using, e.g., a peristaltic pump) is controlled to ensure that the intraocular pressure remains within acceptable limits. Typically, such control is achieved by monitoring the vacuum in the aspiration tube with an electronic sensor connected to a branch of the aspiration tube. The rate at which fluid is supplied to the eye and/or aspirated from the eye is controlled based on the vacuum in the branch as measured by the sensor.

Summary of the Invention

This invention features managing fluid flow in the eye during surgery by detecting vacuum-induced deflections in the tube set itself, and controlling the fluid flow rate based on the detected deflections. As a result, the detection component (e.g., a vacuum sensor) is isolated from the fluids in the tube set. This minimizes both the risk of contaminating the sensor with fluid aspirated from the patient, and the danger of so-called "cross-contamination" in which subsequent patients are exposed to the aspirated fluid of a prior patient.

In one general aspect of the invention, a portion of the tube set through which fluid is supplied to and withdrawn from the eye is constructed to deflect in a selected manner in response to the vacuum level in the tube set, and the rate at which fluid is withdrawn from the eye is controlled based on signals produced by a sensor positioned to detect the deflections.

Preferred embodiments include the following features.

The tube set includes a fluid reservoir, and the deflecting portion of the tube set is a diaphragm disposed on the reservoir. The reservoir and diaphragm are configured so that the diaphragm surface that is exposed to fluid contacts the fluid over substantially all of its area, and the reservoir is configured to be substantially filled with fluid from the tube set. As a result, even small vacuum changes are rapidly and accurately conveyed through the diaphragm to the sensor. Accordingly, the response time of the system components that control fluid aspiration is reduced, and the fluid flow rate through the eye is more accurately maintained within the required range.

Preferably, the tube set and the reservoir are constructed as an integral unit from a single piece of material. The tube set may be disposable (in which case,

the material is, e.g., plastic) or reusable (and made from a material such as silicone rubber).

The thickness of the diaphragm is selected so that the diaphragm deflects in the selected manner in response to vacuum levels in the tube set. For example, the deflection response is linear with respect to pressure changes. Preferably, the diaphragm thickness is in the range of 0.005 inches to 0.006 inches. The diaphragm is made from silicone rubber.

A coupling medium disposed between the deflecting portion and the deflection sensor transmits the deflections. The coupling medium includes a hydraulic force transmitting material, e.g., silicone gel, or other suitable media, such as air. When silicone gel or other hydraulic materials are used, a totally hydraulic vacuum sensing system is provided. Such hydraulic materials are particularly responsive to and capable of transmitting forces caused by deflections of the diaphragm, and provide more faithful force transmission between the diaphragm and the sensor.

The controller responds to the signals from the sensor by adjusting the speed of a pump that is disposed to engage the tube set to withdraw the fluid from the eye. The pump is preferably peristaltic.

In another aspect of the invention, the tube set and its fluid reservoir and diaphragm are received by a housing, and the deflection sensor is mounted on the housing adjacent to the diaphragm.

Preferred embodiments include the following features.

The housing includes a recess configured to receive the reservoir, and a mechanism for urging the reservoir into the recess to seal the diaphragm against a surface of the recess adjacent to the sensor. The sensor and the diaphragm are disposed adjacent to opposite sides of the surface, and the surface includes an opening between opposite sides.

The sealed interface between the diaphragm and the sensor efficiently transfers the vacuum-induced deflections of the diaphragm to the sensor. As a result, accuracy and response time are not compromised by the isolation between the fluids and the sensor that the diaphragm provides.

The housing includes a door movable between an open position, which allows the tube set to be installed in and removed from the housing, and a closed position in which the tube set is retained in the housing. A spring-biased plunger in the housing urges the reservoir into the recess (and seals the diaphragm against the recessed surface) when the door is closed. Closing the door also causes a section of the tube set to be urged against the peristaltic pump; the section of tube is released from the pump when the door is moved to the open position.

In yet another aspect of the invention, the tube set -- including at least the portions through which irrigating fluid is supplied to and withdrawn from the eye and the reservoir -- are constructed as an integral unit from a single piece of material.

Providing the reservoir as an integral part of the tube set dramatically simplifies the procedure for setting up the surgical system for use and, after surgery, for preparing the system for use with a subsequent patient. The tube set with its reservoir is installed into and removed from the housing as a unit. There is no need to assemble the various portions of the tube set during set-up, or disassemble the tube set after use.

In preferred embodiments, the tube set is formed by injection molding, and the diaphragm is then attached to the reservoir. A branch of the tube set interconnects the supply and withdrawal portions of the tube set.

Other features and advantages of the invention will become apparent from the following detailed description, and from the claims.

Brief Description of the Drawings

Fig. 1 schematically shows an eye surgery system.

Fig. 2 illustrates two components of the system of Fig. 1: a tube set and a housing (shown in the open position) which receives the tube set.

Fig. 3 is a cross-section of a fluid reservoir of the tube set of Fig. 2.

Fig. 4 illustrates the tube set placed within the housing (which is shown closed and partially cut away to expose a portion of the tube set).

Fig. 5 shows the construction of a pressure sensitive transducer used in the system of Fig. 1.

Fig. 6 is a cross-sectional view of the housing illustrating the positioning of the tube set reservoir and the pressure sensitive transducer.

Description of a Preferred Embodiment

Fig. 1 shows a system 10 for supplying fluids to and withdrawing fluids from the eye during eye surgery, and for monitoring and controlling the fluid flow rate. An IV bottle 12 supplies fresh fluid to a tube set 20 through a spike line 14 inserted into a female luer 15 of tube set 20. The fluid pressure at the input to tube set 20 is determined by the height of the IV bottle above the patient's eye (typically 60 cm). Fluid flows into tube set 20 when a pinch valve 16 is opened by the user, as discussed below.

Irrigation and aspiration tubes 18 and 22 are attached to tube set 20 at female luers 19 and 23, respectively. More specifically, luer 19 is connected to tube set 20 at fitting 17, which also provides a series connection between luer 15 and a similar fitting 25 that receives luer 23. Tube set branches 20a, 20b are acted upon by pinch valves 16, 24 for purposes to be described.

The distal ends of irrigation and aspiration tubes 18 and 22 are inserted into a handpiece 60, including a hydraulic nozzle 13, of a surgical instrument such as a phaco-emulsification unit for manipulation in eye 70.

A peristaltic pump 26 driven by motor 62 induces a vacuum in tube set 20 by alternately contracting and releasing a section 20c of tube set 20. This vacuum draws aspirated fluid from eye 70, through aspiration tube 22 and branch 20c, for disposal into a waste collection container (not shown) via a separate tube connected to tube set 20 at male luer 28.

The operation of motor 62 (and hence of pump 26) and pinch valves 16, 24 is managed by a controller 66, which in turn responds to user controls 68, as described in detail below. Among other parameters, user controls 68 include settings for a range of fluid flow rates and a maximum vacuum level in tube set 20. Controller 66 includes a programmed microprocessor (not separately shown) which responds to user controls 68, as well as the vacuum level in tube set 20 as measured by transducer 48 (described below), by adjusting the speed of motor 62 (and pump 26) to maintain the flow rate within the range set by the user and to avoid the vacuum level in tube set 20 exceeding the maximum set by the user. If necessary, controller 66 also closes pinch valve 16 (to stop further flow of irrigation fluid), opens pinch valve 24 (to reduce the vacuum level in tube set 20 to zero), and/or stops pump 26 to keep the flow rate within the selected range and prevent the maximum vacuum level from being exceeded.

Referring also to Figs. 2 and 3, transducer 48 measures the vacuum level by sensing vacuum-induced strain on a diaphragm 40 of a sealed, cylindrical reservoir 30 that forms part of tube set 20. Specifically, reservoir 30 is connected to the remainder of tube set 20 at fitting 25 (which includes a port 85 for admitting fluid into reservoir 30). Reservoir 30 thus is in the path of fluid aspirated from eye 70.

The lower wall (Fig. 3) of reservoir 30 comprises a thin (relative to the other walls of reservoir 30), circular diaphragm 40, which is tightly stretched over

and rigidly attached to the lower surface of reservoir side walls 80 to form (with upper wall 82) a chamber 84. Fluid enters chamber 84 through port 85 in fitting 25. The thickness, diameter and material (e.g., silicone rubber) of diaphragm 40 is selected so that diaphragm 40 expands and contracts in a well-defined manner (described below) in response to vacuum-level changes within chamber 84. For example, diaphragm 30 is between 0.005 inch thick and 0.006 inch thick. In general, to use a thicker or thinner diaphragm 40, the diameter of diaphragm 40 must be larger or smaller, respectively. Transducer 48 detects the vacuum-induced expansion and compression of diaphragm 40 and converts this information into electrical signals, which are sent to controller 66 (Fig. 1) for processing.

Upper wall 82 and side walls 80 of reservoir 30 are substantially thicker than diaphragm 40 (e.g., one-eighth inch thick) to maintain the structural integrity of reservoir 30 during use, as discussed in more detail below. With the exception of diaphragm 40, tube set 20 -- including reservoir 30 and the various branches 20a, 20b, 20c and fittings (e.g., luers 15, 19, 23, and 28) -- is formed as an integral unit from a single piece of material. Put another way, a health care provider or other user of system 10 need not assemble tube set 20 (i.e., interconnect segments 20a-20c, fittings 17, 25, luers 15, 19, 23, and 28, and reservoir 30) before use, or disassemble tube set 20 after use.

In this embodiment, tube set 20 is formed by injection molding. The material used does not depend upon whether tube set 20 is to be used in only one surgical procedure (i.e., disposed of after a single-use) or in multiple procedures. Silicone rubber is a good choice of material because it is autoclavable, elastic (to withstand the pumping action applied to it by pump 26) and biocompatible. Alternatively, tube set 20 may be made from another material which need not be

autoclavable, but rather disposable after a single use. In either case, after injection molding, diaphragm 40 is secured to side walls 80 by any suitable sealing technique, e.g., using silicone adhesive.

As shown in Figs. 2 and 4, tube set 20 is installed as a unit into a housing 32, which contains peristaltic pump 26 (and motor 62), pinch valves 16, 24 (and their associated plungers 50 and driving solenoids 52), and an electronic transducer 48 for measuring the vacuum level within reservoir chamber 84. An interior channel 72 in housing 32 is sized and shaped to receive the various fittings and branches of tube set 20 for proper positioning. That is, luers 15, 19, 23, and 28 fit snugly within correspondingly-shaped seats in channel 72 so that: (1) reservoir 30 is received by a cylindrical recess 45 of channel 72; (2) tube sections 20a, 20b are located over pinch valve plungers 50; and (3) tube section 20c is wrapped partially around the perimeter of peristaltic pump 26. Note that transducer 48 defines the lower boundary of recess 45 and abuts reservoir diaphragm 40.

The user loads tube set 20 into housing 32 by placing tube set 20 within channel 72 in the orientation discussed above. In addition, a square boss 34 on the exterior of section 20c (and integrally formed with the remainder of tube set 20 during molding) fits into a correspondingly-shaped recess in channel 72 (Fig. 4). Boss 34 helps avoid creeping of tube section 20c in response to the operation of pump 26. Spike line 14 is then attached to tube set 20 at luer 15, and irrigation and aspiration tubes 18 and 22 are attached to tube set 20 at luers 19 and 23. Finally, a drainage tube is connected to luer 28.

After tube set 20 has been loaded, the user closes spring loaded door 36 by pivoting door around hinge 42, and latches door 36 shut (as shown in Fig. 4). In the closed position, door 36 completely covers tube set 20

and secures it in position within housing 32. Closing door 36 also engages several operating features of housing 32. For example, a spring loaded plunger 46 on door 36 engages upper wall 82 of reservoir 30 and firmly urges reservoir 30 (and hence diaphragm 40) against transducer 48 at the lower surface of recess 45. The force of the spring 47 (Fig. 6) is sufficient to create an air-tight seal between the lower periphery of walls 80 and transducer 48. Walls 80, 82 must therefore be sufficiently thick to keep reservoir 30 from being crushed by the spring force.

Closing door 36 also activates a rack and pinion 38 attached to a slidable block 39 of housing 32. In response to rack and pinion 38, block 39 slides toward pump 26 to capture tube set section 20c between pump rollers 27 and a curved peripheral surface 41 of block 39. During operation, as the head of peristaltic pump 26 rotates (clockwise in Figs. 2 and 4), a set of peripheral rollers 27 alternately compress (against surface 41) and release regions of tube section 20c. This action creates an even flow of fluid through tube set 20 to minimize turbulence in the eye.

Finally, a pair of protrusions 44 located on the underside of door 36 directly opposite pinch valve plungers 50 slightly engage tube set sections 20a, 20b when door 36 is closed. Pinch valves 16, 24 close by compressing tube set sections 20a, 20b against protrusions 44 with plungers 50.

Referring to Fig. 5, transducer 48 comprises an electronic sensor 57 secured within a cylindrical base 52. Base 52 is secured to the underside of housing 32 so that a circular wall 51 at one end of base 52 defines the lower limit of reservoir recess 45 (Fig. 2). A round hole 54 approximately 1/32 inch in diameter is located at the radial center of wall 51 and is centered over the face of sensor 57 (and also under diaphragm 40 when reservoir 30 is installed). Sensor 57 (commercially

available from Motorola) contains a sensing circuit etched on a silicone wafer in the manner of a strain gauge and is mounted on a substrate, which in turn is threaded into an open end of base 52 opposite wall 51 so that the face of sensor 57 abuts the underside of wall 51.

Sensor 57 is sealed to base 52 using an O-ring 53. The space between sensor 57 and base 52 enclosed by O-ring 53, including hole 54, is filled with coupling medium 55, such as silicone gel. The silicone gel coupling medium 55 hydraulically transmits forces generated by deflections of diaphragm 40 to sensor 57. That is, the silicone gel displaces all of the air between diaphragm 40 and sensor 57, thus creating a totally hydraulic vacuum sensing system. Silicone gel performs well under surgical conditions because it is particularly responsive to and capable of transmitting forces caused by deflections of the diaphragm. Silicone gel thus provides faithful force transmission between the diaphragm and the sensor.

Referring also to Fig. 6, the relative positions of reservoir diaphragm 40 and the components of transducer 48 (when housing 32 is closed) are shown. Spring-loaded plunger 46 urges reservoir 30 firmly against wall 51, thereby creating a tight vacuum seal between diaphragm 40 and wall 51. As a result, vacuum level changes in diaphragm chamber 84 cause diaphragm 40 to expand toward or pull away from wall 51, as the case may be, thereby applying a vacuum force to sensor 57 through hole 54. Sensor 57 serves as an electronic strain gauge, and converts the vacuum forces experienced by diaphragm 40 into electrical signals that are transmitted to controller 66 via connector 56 (Fig. 5).

In operation, prior to the surgical procedure, the user places a sterile tube set 20 in housing 32, attaches the ancillary fluid tubes 14, 18, 22, and closes door 36, all as discussed above. The acceptable range of fluid

flow rates and maximum vacuum level are set using controls 68. When the surgical procedure is started, system 10 is "primed" by completely filling tube set 20 -- including reservoir 30 -- with irrigation fluid from IV bottle 12. For example, priming is accomplished by repeatedly applying a relatively strong vacuum to tube set 20 several times and allowing fluid to flow into tube set 20. Eliminating air or other gases from reservoir 30 or other parts of tube set 20 increases the response time of system 10 to vacuum changes, as discussed below.

During the surgical procedure, clean irrigating fluid flows into the eye from IV bottle 12, through tube set section 20a (and past pinch valve 16, which is opened by controller 66), and through irrigation line 18. (Pinch valve 24 is normally closed by controller 66, as will be explained.) Controller 66 operates pump 26 (via motor 62) to continuously aspirate fluid from the eye (via line 22 and tube set section 20c) into drainage. Increasing the speed of pump 26 increases the vacuum applied to tube set 20, thereby withdrawing fluid from the eye at a faster rate. Conversely, reducing the speed of pump 26 lowers the vacuum applied to tube set 20, and thus slows the aspiration rate.

Transducer 48 measures the vacuum created in tube set 20 via reservoir diaphragm 40, as discussed above. Due to its location at the junction of aspiration tube 22 and tube set section 20c, reservoir 30 receives the aspirated fluid directly from the eye. Because reservoir 30 is completely filled with fluid during the priming procedure, changes in vacuum level rapidly induce corresponding deflections of reservoir diaphragm 40, causing diaphragm 40 to attempt to expand (as the vacuum level decreases) and contract (in response to increasing vacuum levels within tube set 20).

The thickness, diameter and material of reservoir diaphragm 40 provides a one-to-one correspondence between

the vacuum level in reservoir 30 and the deflection of diaphragm 40 within a range from 0 mm Hg - 500 mm Hg.

Sensor 57 converts the vacuum forces generated by diaphragm 40 into corresponding electrical signals that represent the vacuum level within reservoir 30. Controller 66 uses these signals to determine whether the speed of pump 26 should be increased or decreased to maintain the flow rate of within the preset range and the vacuum level in tube set 20 below the preset maximum.

Specifically, controller 66 responds to decreases in the flow rate, as indicated by the detected vacuum level, by increasing the speed of pump 26 to increase the vacuum applied to tube set 20 and withdraw fluid from the eye at a greater rate. Conversely, as flow rate increases (as indicated by an increase in the vacuum applied by diaphragm 40 to sensor 57), controller 66 slows pump 26, thereby maintaining the flow rate within the desired range.

If a sudden event (such as clogging of the surgical instrument) occurs which causes the vacuum level measured by transducer 48 to increase rapidly, controller 66 opens pinch valve 24, to reduce the vacuum level in tube set 20 to zero. This avoids damage which would otherwise occur if intraocular pressure were allowed to build unchecked.

When the surgical procedure has been completed, tube set 20 (including reservoir 30) is removed from housing 32 as single unit by simply detaching tube set 20 from external lines 14, 18, 22 and drainage. Tube set 20 is then either discarded or sterilized for use with a subsequent patient. In any event, system 10 is readied for use with a subsequent patient by simply installing another (or a resterilized) tube set 20 as a unit in housing 32.

Reservoir diaphragm 40 provides a sealed interface between the aspirated fluid in reservoir 30 and transducer 48. Accordingly, fluid aspirated from the

patient's eye is isolated from transducer 48. Among other advantages, contamination (and potential fouling) of transducer 48 is avoided, as is so-called "cross-contamination" (i.e., exposing a subsequent patient to fluids aspirated from a previous patient on whom system 10 was used).

Other embodiments are within the scope of the following claims.

For example, reservoir 30 and diaphragm 40 may be manufactured as a single, integral unit from a unitary piece of material. That is, diaphragm 40 may be formed at the same time that the remainder of reservoir 30 is fabricated, thereby eliminating the need for a separate attachment step. Reservoir 30 may be detachable from the remainder of tube set 20, rather than being integrally formed with it.

Other coupling media 55 may be used in place of the silicone gel. For example, other hydraulic materials (e.g., fluids) may be used, or coupling media 55 may be air or another gas.

What is claimed is:

1. Apparatus for use in eye surgery, comprising

a tube set through which fluid is supplied to and withdrawn from the eye, a portion of said tube set being constructed to deflect in a selected manner in response to a vacuum level in said tube set,

a deflection sensor disposed adjacent to said portion of said tube set, and

a controller for controlling a rate at which fluid is withdrawn from the eye based on signals produced by said sensor in response to the deflections in said portion of said tube set.

2. The apparatus of claim 1 wherein said tube set includes a fluid reservoir, said portion of said tube set comprising a diaphragm disposed on said reservoir.

3. The apparatus of claim 2 wherein said reservoir and said diaphragm are configured so that a surface of said diaphragm that is exposed to fluid in said reservoir from said tube set is in contact with the fluid over substantially all of its area.

4. The apparatus of claim 3 wherein said reservoir is configured to be substantially filled with fluid from said tube set.

5. The apparatus of claim 2 wherein said tube set and said reservoir are constructed as an integral unit from a single piece of material.

6. The apparatus of claim 5 wherein said material comprises plastic.

7. The apparatus of claim 5 wherein said material comprises silicone rubber.

8. The apparatus of claim 2 wherein said diaphragm has a thickness selected to deflect in said selected manner in response to the vacuum level in said tube set.

9. The apparatus of claim 8 wherein said thickness is selected so that said diaphragm deflects linearly over a pressure range of 0 mm Hg to 500 mm Hg.

10. The apparatus of claim 8 wherein said diaphragm has a thickness in the range of 0.005 inches to 0.006 inches.

11. The apparatus of claim 2 wherein said diaphragm includes silicone rubber.

12. The apparatus of claim 1 further comprising a pump disposed to engage said tube set to induce said vacuum and withdraw the fluid from the eye, said controller adjusting the speed of said pump in response to said signals produced by said sensor.

13. The apparatus of claim 12 wherein said pump is a peristaltic pump.

14. The apparatus of claim 1 further comprising a coupling medium disposed between said portion and said deflection sensor for transmitting said deflections.

15. The apparatus of claim 14 wherein said coupling medium includes hydraulic material.

16. The apparatus of claim 15 wherein said coupling medium is silicone gel.

17. The apparatus of claim 14 wherein said coupling medium is air.

18. Apparatus for use in eye surgery, comprising

a tube set through which fluid is supplied to and withdrawn from the eye, said tube set including a fluid reservoir having a diaphragm disposed thereon that deflects in response to a vacuum level in said reservoir,

a housing configured to receive said tube set, and

a sensor mounted on said housing adjacent to said diaphragm for detecting deflections of said diaphragm.

19. The apparatus of claim 18 wherein said housing comprises

a recess configured to receive said reservoir so that said diaphragm abuts a surface of said recess adjacent to said sensor, and

a mechanism for urging said reservoir into said recess to seal said diaphragm against said surface.

20. The apparatus of claim 19 wherein sensor and said diaphragm are disposed adjacent to opposite sides of said surface, and further comprising an opening in said surface between said opposite sides.

21. The apparatus of claim 20 further comprising a coupling medium disposed in said opening.

22. The apparatus of claim 21 wherein said coupling medium includes hydraulic material.

23. The apparatus of claim 22 wherein said coupling medium is silicone gel.

24. The apparatus of claim 21 wherein said coupling medium is air.

25. The apparatus of claim 18 wherein said sensor is constructed to produce electrical signals representing the vacuum level in said reservoir in response to deflections of said diaphragm, and further comprising a controller for controlling a rate at which fluid is withdrawn from the eye based on said electrical signals.

26. The apparatus of claim 25 further comprising a peristaltic pump mounted on said housing and disposed to engage said tube set to induce said vacuum and withdraw the fluid from the eye, said controller adjusting the speed of said pump in response to said electrical signals produced by said sensor.

27. The apparatus of claim 18 wherein said housing includes a door movable between an open position to allow said tube set to be installed in and removed from said housing, and a closed position in which said tube set is retained in said housing.

28. The apparatus of claim 20 wherein said housing further comprises a spring-biased plunger for urging said reservoir into a recess in said housing adjacent to said sensor when said door is in the closed position.

29. The apparatus of claim 27 further comprising

a peristaltic pump mounted on said housing and disposed to engage said tube set to induce said vacuum and withdraw the fluid from the eye, and

a mechanism for urging a section of said tube set against said peristaltic pump when said door is in the closed position, and releasing said section of said tube from said pump when said door is in the open position.

30. Apparatus for use in eye surgery, comprising

a tube set through which fluid is supplied to and withdrawn from the eye, said tube set including a fluid reservoir having a diaphragm disposed thereon that deflects in response to a vacuum level in said reservoir,

a housing configured to receive said tube set,

a sensor mounted on said housing adjacent to said diaphragm for detecting deflections of said diaphragm, and

hydraulic material disposed between said sensor and said diaphragm.

31. The apparatus of claim 30 wherein said hydraulic material is silicone gel.

32. A tube set through which fluid is applied to and withdrawn from the eye during eye surgery, said tube set comprising

a first portion configured to receive the fluid from a supply and couple the supplied fluid to the eye,

a second portion configured to receive fluid withdrawn from the eye and couple the withdrawn fluid to drainage,

a fluid reservoir coupled to said second portion of said tube set, and

a diaphragm disposed on said fluid reservoir, said diaphragm being constructed to deflect in a selected manner in response to a vacuum level in said reservoir,

at least said first portion, said second portion, and said reservoir being constructed as an integral unit from a single piece of material.

33. The tube set of claim 32 wherein said material comprises plastic.

34. The tube set of claim 32 wherein said material comprises silicone rubber.

35. The tube set of claim 32 further comprising a branch that interconnects said first portion and said second portion.

36. A method of making the tube set of claim 32, comprising forming at least said first portion, said second portion, and said reservoir by injection molding.

37. The method of claim 36 further comprising attaching said diaphragm to said reservoir after said injection molding.

38. A method of controlling fluid pressure in the eye during eye surgery, comprising

supplying fluid to the eye and withdrawing fluid from the eye with tube set a portion of which is constructed to deflect in a selected manner in response to a vacuum level in said tube set,

sensing deflections of said portion of said tube set, and

controlling a rate at which fluid is withdrawn from the eye based on said sensing.

39. The method of claim 38 further comprising transmitting forces induced by said deflections from said portion of said tube set through a coupling medium to a sensor which performs said sensing.

40. The method of claim 39 wherein said transmitting step includes transmitting said forces through a hydraulic material to said sensor.

41. The method of claim 40 wherein said hydraulic material through which said forces are transmitted to said sensor in said transmitting step is silicone gel.

42. The method of claim 39 wherein said transmitting step includes transmitting said forces through air to said sensor.

43. The method of claim 38 wherein said tube set includes a fluid reservoir, said portion of said tube set comprising a diaphragm disposed on said reservoir, said sensing including detecting deflections of said diaphragm.

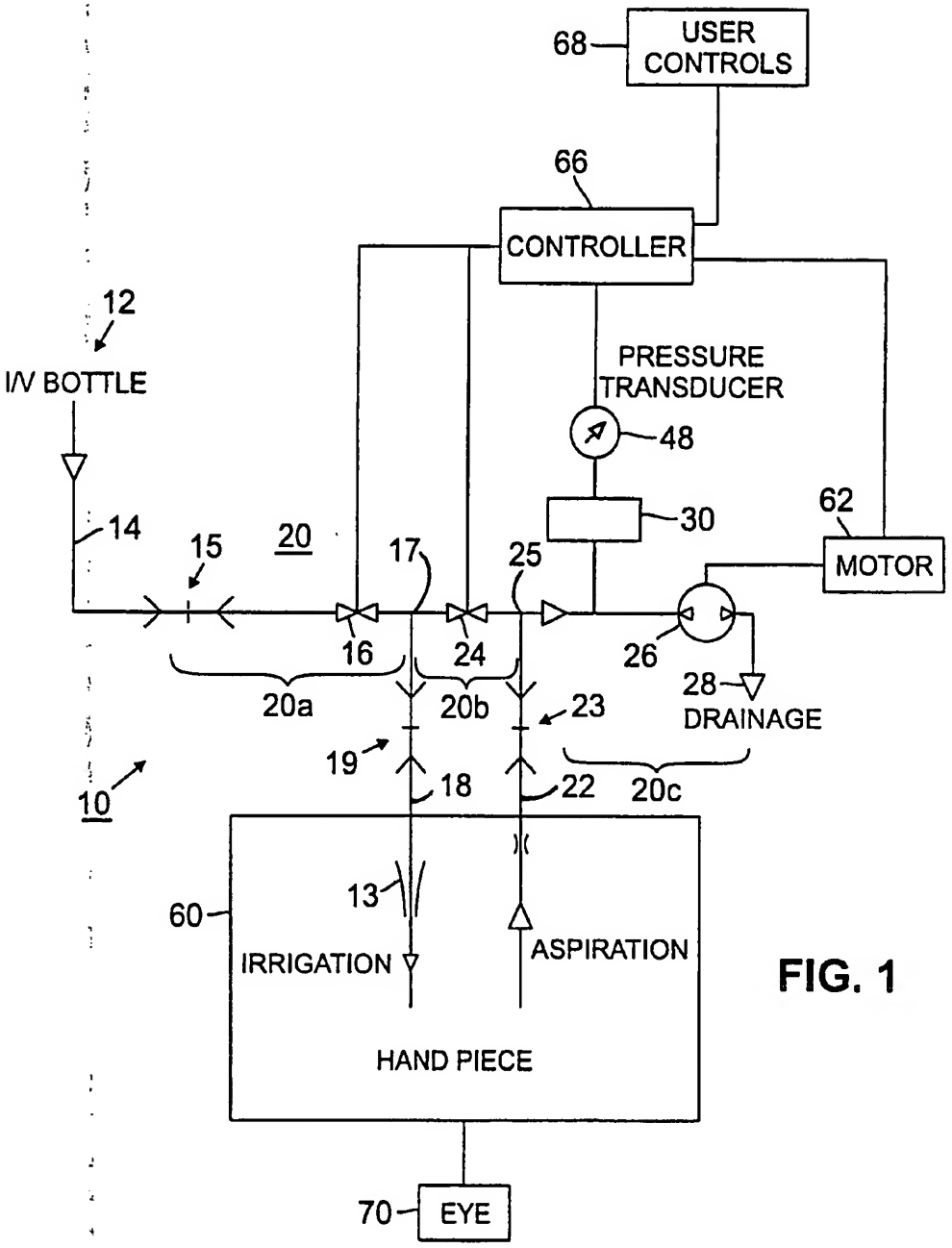

FIG. 1

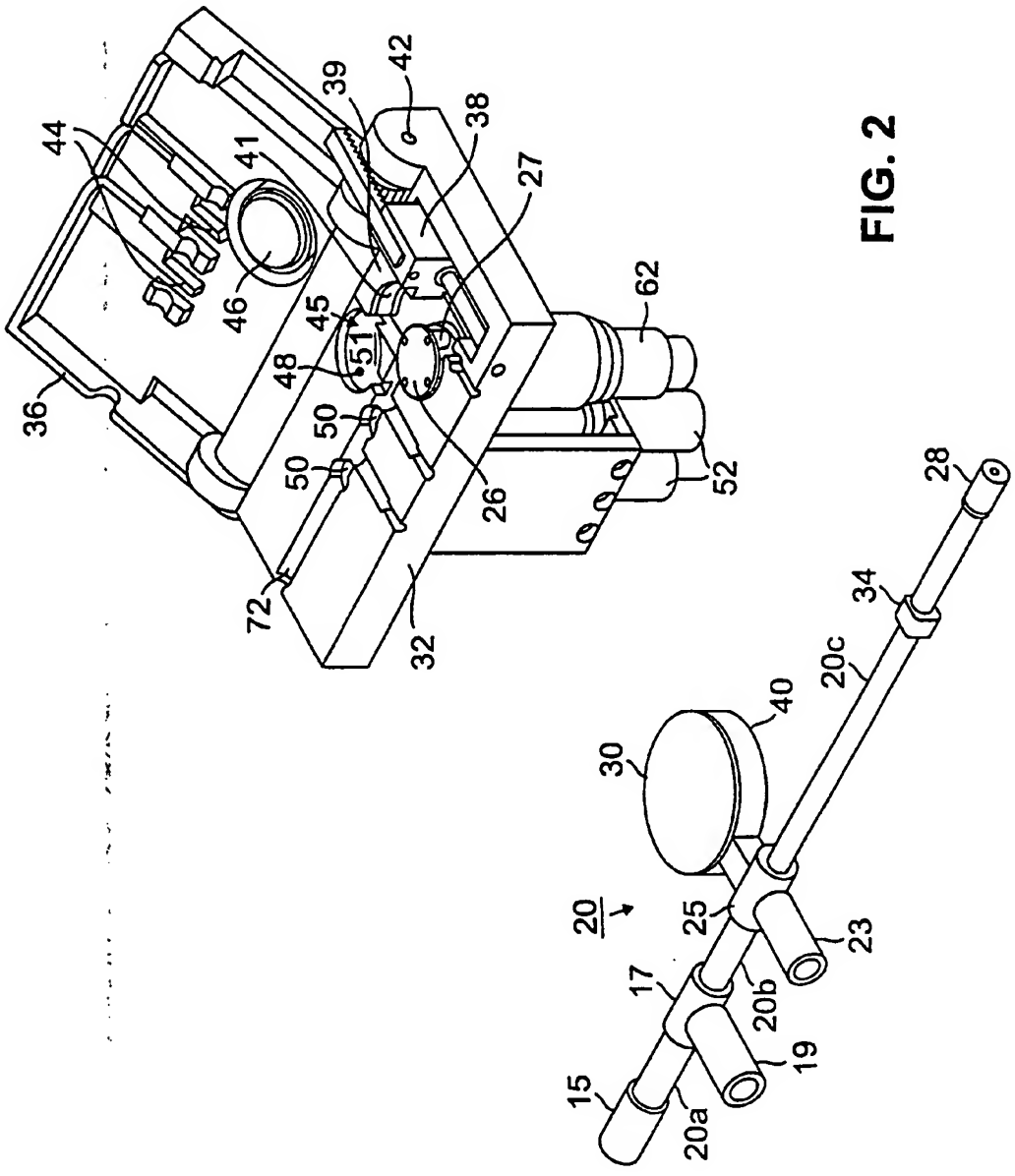

FIG. 2

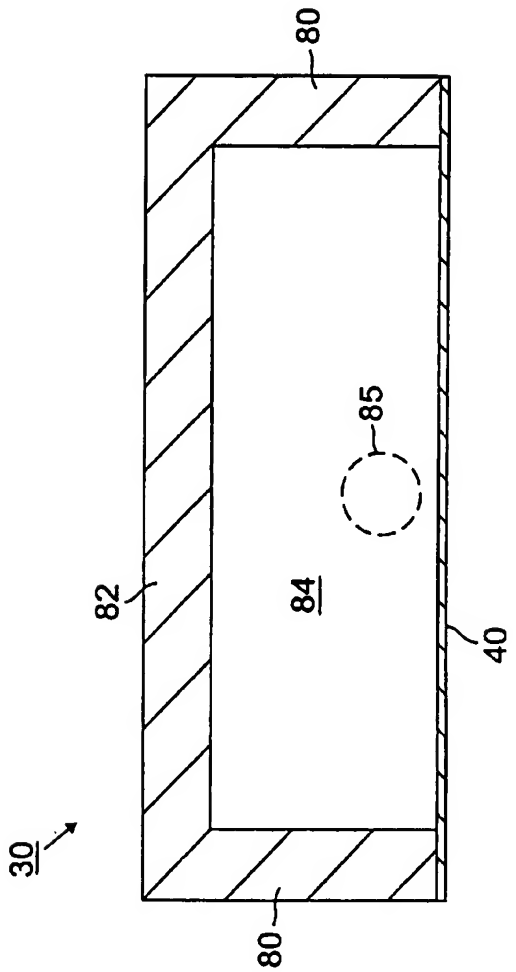

FIG. 3

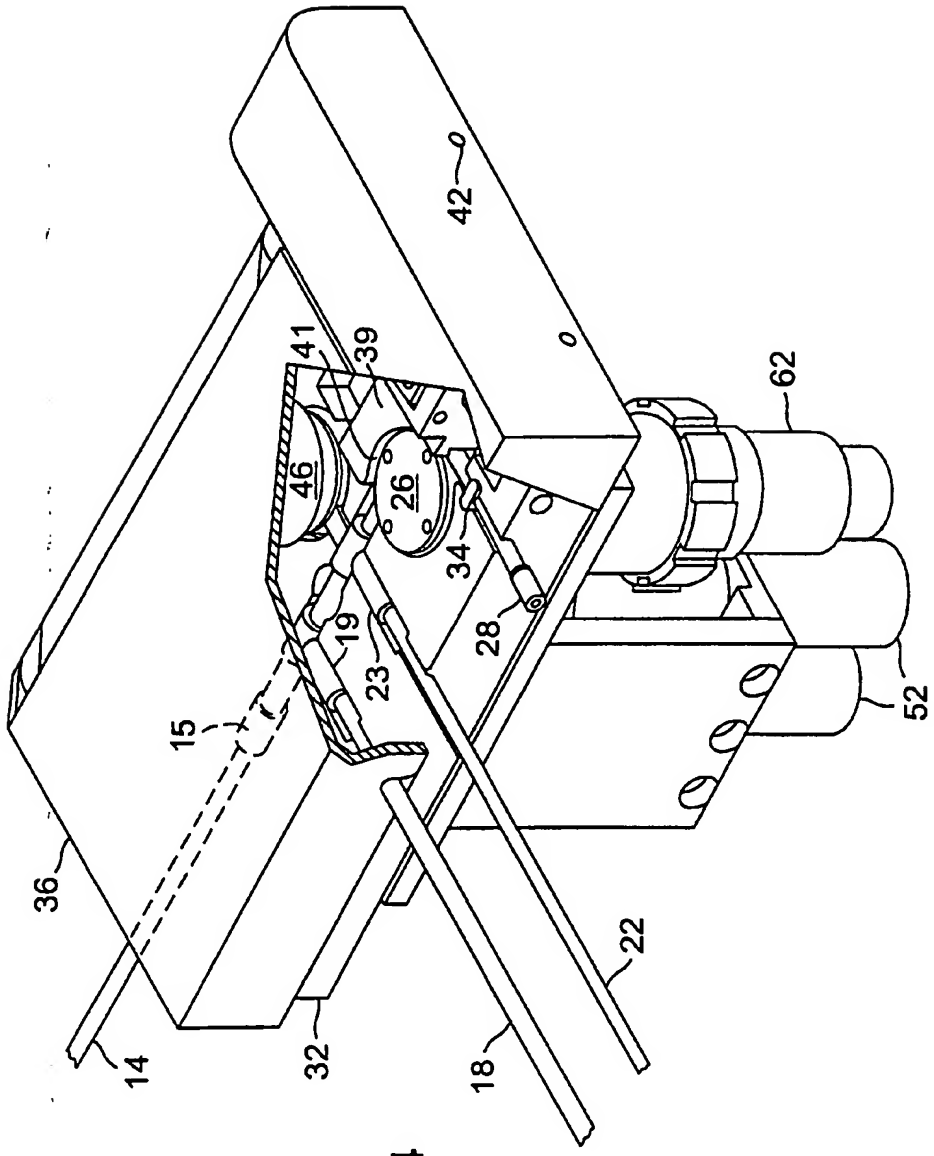

FIG. 4

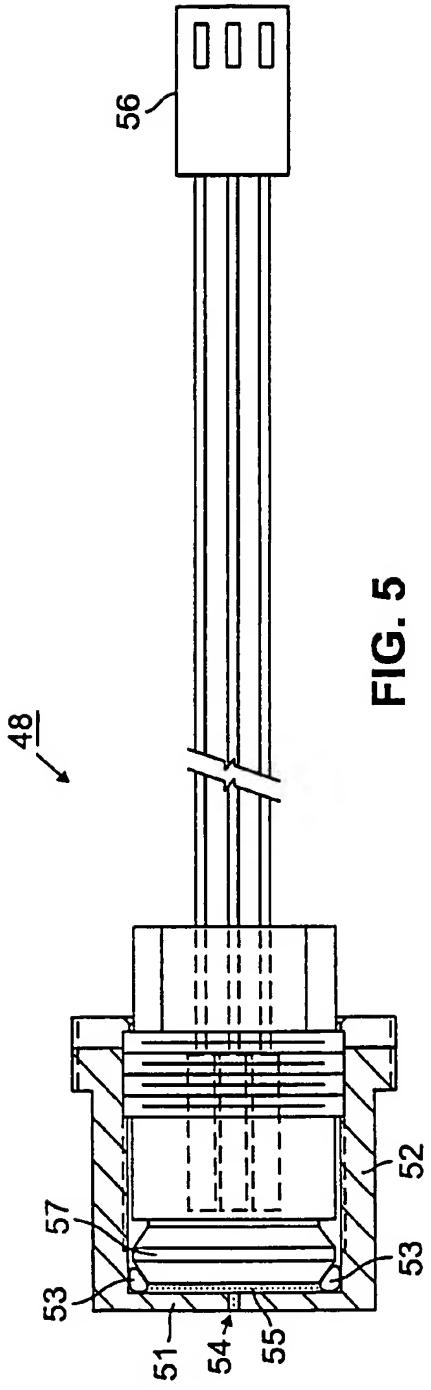

FIG. 5

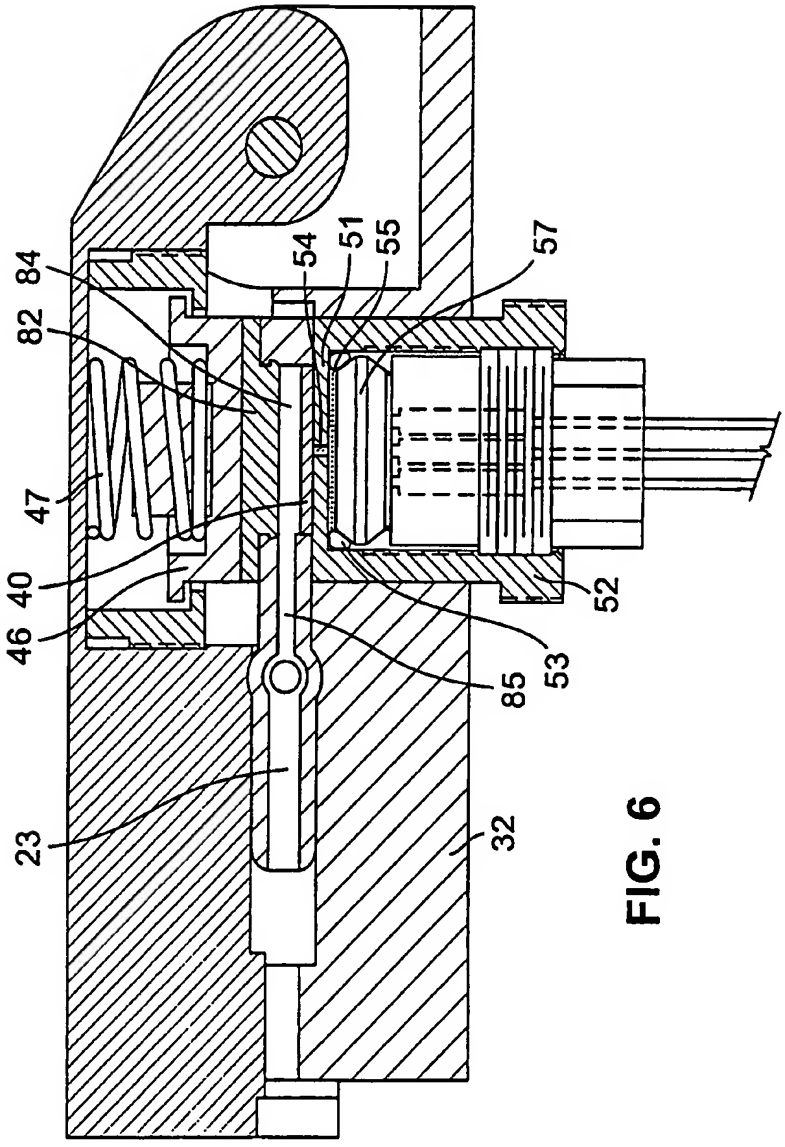

FIG. 6

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/08170

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F9/007 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,93 24082 (ALLERGAN) 9 December 1993	1-14, 17-21, 24-27, 29,32-37
Y	see page 6, line 12 - page 11, line 33; figures 1-6	15,16, 22,23, 28,30,31

X	EP,A,0 180 317 (ARMENIADES) 7 May 1986	1-8,12, 13
A	see page 12, line 21 - page 13, line 38; figures 7,8,4	32,33

Y	US,A,4 993 265 (KOEN EDWARD F ET AL) 19 February 1991	15,16, 22,23, 30,31
	see column 5, line 52 - column 6, line 17; figure 4	

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 September 1996	07. 10. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Moers, R

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INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/US 96/08170

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 372 709 (HOOD ROBERT G) 13 December 1994 see column 5, line 41 - line 64; figure 1	5-7, 32-37
A	WO,A,93 24817 (ALLERGAN) 9 December 1993 see page 8, line 1 - line 23; figure 2	10,11,34
A	EP,A,0 559 602 (ALCON SURGICAL INC ;NESTLE SA (CH)) 8 September 1993 see column 7, line 12 - line 33 see column 8, line 7 - line 24; figures 1,2	5-7, 32-37
Y	US,A,4 227 420 (LAMADRID RENE G) 14 October 1980 see column 5, line 51 - column 6, line 58; figure 1	28

INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/US96/08170

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 38-43
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1(iv)Method for treatm. of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter nal Application No
PCT/US 96/08170

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INTERNATIONAL SEARCH REPORT

.nformation on patent family members

Inter nal Application No
PCT/US 96/08170

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US-A-4227420	14-10-80	NONE	